

NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

**IN RE HUMAN TISSUE PRODUCTS
LIABILITY LITIGATION**

Civ. No. 06-135
MDL No. 1763

THIS DOCUMENT RELATES TO:

**LINDA GRAVES, MATTHEW GRAVES,
DAVID GRAVES, MARIAN TANGHE,
ARTHUR TANGHE, CLARA GRAVES and
ALBERT GRAVES,**

Civ. No. 06-5655

Plaintiffs,

OPINION

v.

HON. WILLIAM J. MARTINI

**BIOMEDICAL TISSUE SERVICES, LTD.,
MICHAEL MASTROMARINO, THOMAS E.
BURGER FUNERAL HOME, INC.,
THOMAS E. BURGER, JASON GANO,
REGENERATION TECHNOLOGIES, INC.,
LIFECCELL CORP., TUTOGEN MEDICAL,
INC., BLOOD & TISSUE CENTER OF
CENTRAL TX, and LOST MOUNTAIN
TISSUE BANK,**

Defendants.

MARTINI, U.S.D.J.

This is an action brought by the relatives of Bradley Graves (“Graves”) who claim that the defendants harvested and processed tissue and bones from Graves’s body without

proper consent.¹ Presently before the Court are motions for summary judgment filed by those defendants who processed Graves's tissue and bones after they were harvested from his body. The plaintiffs oppose the motions for summary judgment. For the following reasons, the motions for summary judgment filed by defendants Regeneration Technologies, Inc. ("RTI"), LifeCell Corp. ("LifeCell"), Lost Mountain Tissue Bank ("Lost Mountain"), and Tutogen Medical, Inc. ("Tutogen") are **DENIED**.

BACKGROUND & PROCEDURAL HISTORY

The plaintiffs in this action are the wife, two sons, parents, and parents-in-law of Graves. As stated in the Complaint, Graves died on July 31, 2005 from complications arising from cancer. Following his death, the plaintiffs contracted with Thomas E. Burger Funeral Home, Inc. ("Burger Funeral Home") for funeral arrangements and cremation services. The plaintiffs allege that Burger Funeral Home, after taking possession of Graves's body for cremation, allowed Biomedical Tissue Services, Inc. ("BTS") and Michael Mastromarino to harvest (*i.e.*, remove) tissue and bones from Graves's body for medical research and implantation. The plaintiffs allege that neither they nor Graves consented to the harvesting of the body parts. Furthermore, the plaintiffs claim that Burger Funeral Home never disclosed that such harvesting would occur.

The plaintiffs allege that the defendants' actions caused them pain and suffering as well as emotional distress. Thus, they instituted this action on June 30, 2006 by filing a

¹ Criminal proceedings against certain of the defendants related to the alleged illegal harvesting of body parts are currently pending in state courts.

complaint in the State of New York Supreme Court, Monroe County. The defendants removed this case to the United States District Court for the Western District of New York, and then, the Judicial Panel on Multidistrict Litigation transferred the action to this Court for consolidation with *In re Human Tissue Products Liability Litigation*, MDL No. 1763.

In January 2007, defendants Blood and Tissue Center of Central Texas (“BTCCT”), LifeCell, Tutogen, RTI, and Lost Mountain (collectively, the “Tissue Bank Defendants”) filed separate motions for summary judgment pursuant to Fed. R. Civ. P. 56. Each of the defendants is a tissue bank that allegedly received tissue and body parts from BTS.

The plaintiffs’ Complaint, while containing ten counts, only names the Tissue Bank Defendants in four of the counts. The plaintiffs contend that the Tissue Bank Defendants willfully disregarded federal and state regulations “regarding the procedures for obtaining consent, harvesting organs and/or tissue, testing harvested organs and/or tissue, and transplant of harvested organs and/or tissue.” (Compl. ¶¶ 34, 37.) Additionally, the Complaint states that the Tissue Bank Defendants failed in their legal duty to ensure that proper consents were obtained and that proper harvesting procedures were followed. (*Id.* ¶¶ 67-69, 75-77.) The remaining counts of the Complaint pertain to the other non-moving defendants.

Each of the Tissue Bank Defendants has moved for summary judgment on Counts

One, Two, Eight, and Nine of the Complaint by relying on the New York Anatomical Gift Act, N.Y. Pub. Health Law §§ 4300-4309.² This act provides a good-faith defense to certain recipients of human tissue and immunizes them from liability. The plaintiffs oppose the motions. The Tissue Bank Defendants' motions are now before the Court.

STANDARD OF REVIEW

Summary judgment is appropriate when “the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(c). The burden of showing that no genuine issue of material fact exists rests initially on the moving party. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). A litigant may discharge this burden by exposing “the absence of evidence to support the nonmoving party’s case.” *Id.* at 325. In evaluating a summary judgment motion, a court must view all evidence in the light most favorable to the nonmoving party. *See Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986); *Goodman v. Mead Johnson & Co.*, 534 F.2d 566, 573 (3d Cir. 1976).

Once the moving party has made a properly supported motion for summary judgment, the burden shifts to the nonmoving party to “set forth specific facts showing

² Defendant BTCCT has additionally moved for summary judgment based on the plaintiffs’ failure to establish standing. Those arguments are addressed in the Court’s separate Opinion addressing BTCCT’s summary judgment motion.

that there is a genuine issue for trial.” Fed. R. Civ. P. 56(e); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986). A party cannot simply rest on the allegations contained in his complaint in opposition to a properly supported summary judgment motion. Fed. R. Civ. P. 56 (providing that the party opposing summary judgment may not rest upon the mere allegations or denials of the pleading, but must, by affidavits or as otherwise provided in the rule, set forth specific facts showing that there is a genuine issue for trial).

If the non-moving party fails to sufficiently support its opposition by affidavits, depositions, answers to interrogatories, admissions on file, and pleadings, a court may nevertheless deny or stay summary judgment if “it appear[s] from the affidavits of a party opposing the motion that the party cannot for reasons stated present by affidavit facts essential to justify the party’s opposition.” Fed. R. Civ. P. 56(f). A party moving pursuant to Rule 56(f), however, must submit an affidavit explaining “what particular information is sought; how, if uncovered, it would preclude summary judgment; and why it has not previously been obtained.” *Doe v. Abington Friends School*, 480 F.3d 252, 256 (3d Cir. 2007) (citations omitted). For purposes of Rule 56(f), a mere legal memorandum is insufficient, and failure to comply with Rule 56(f) in all, but the most exceptional cases, is “fatal to a claim of insufficient discovery on appeal.” *Bradley v. United States*, 299 F.3d 197, 207 (3d Cir. 2002); *see also Radich v. Goode*, 886 F.2d 1391, 1394 (3d Cir. 1989).

DISCUSSION

In their summary judgment motions, LifeCell, RTI, Lost Mountain, and Tutogen³ argue that the facially valid consent forms supplied by BTS complied with the terms of the New York Anatomical Gift Act (the “Gift Act”), and therefore, the good-faith defense bars the plaintiffs’ claims against the Tissue Bank Defendants.⁴ The Court, reserving judgment on the final determination of good faith, finds that summary judgment in favor of the Tissue Bank Defendants at this time would be premature without further discovery.

The Gift Act establishes the conditions and methods for executing an anatomical gift (*i.e.*, a donation of a body or body parts). It sets forth who may authorize an anatomical gift upon death, and the manner by which the decedent, or his (or her) next of kin, may consent to an anatomical gift. *See* N.Y. Pub. Health Law §§ 4300-4303. Additionally, the Gift Act protects donees of an anatomical gift, who act in good faith and in accordance with the statute, from civil suits and criminal prosecution related to receiving the gift. *See* N.Y. Pub. Health Law § 4306(3). Specifically, the statute states:

A person who acts in good faith in accord with the terms of this article or with the anatomical gift laws of another state is not

³ BTCCT also joins in the motions for summary judgment on the issue of good-faith immunity. However, as discussed in this Court’s separate Opinion addressing BTCCT’s summary judgment motion, all claims against BTCCT are dismissed for lack of standing.

⁴ Since this case was removed by the defendants based upon diversity jurisdiction, the Court must apply the law that the transferor court would have applied. *See* 17 JAMES WM. MOORE ET AL., MOORE’S FEDERAL PRACTICE ¶ 112.07 (3d ed. 1997 & Supp. 2007). Here, the Western District of New York would have applied New York law in assessing the validity of the donor consent forms and the applicability of a good-faith defense to liability.

liable for damages in any civil action or subject to prosecution in any criminal proceeding for his act.

Id.

Good-faith immunity under the Gift Act, however, is not absolute. Specifically, a donee is prohibited from accepting an anatomical gift under the following circumstances:

- (a) the donee has actual notice of contrary indication by the decedent;
- (b) where the donor has not properly executed an organ donor card, driver's license authorization to make an anatomical gift ... or otherwise given written authorization ... or has revoked any such authorization, and the gift is opposed by [the next of kin]; or
- (c) the donee has reason to believe that an anatomical gift is contrary to the decedent's religious or moral beliefs.

Id. § 4301(3).

Applying these provisions, one New York court held that a tissue bank that relies on facially valid documentation of consent provided by a third party is immune from suits brought by the decedent's kin. *See Nicoletta v. Rochester Eye & Human Parts Bank, Inc.*, 136 Misc. 2d 1065, 1069 (N.Y. Sup. Ct. 1987). In *Nicoletta*, the court granted summary judgment in favor of an eye bank in a suit brought by the decedent's father, who alleged physical and emotional injuries when he learned that his son's eyes were removed for donation based on consent provided by a woman claiming to be the decedent's wife. *Id.*

Although the woman was not legally authorized to make the consent for donation because she was not, in fact, his legal wife, the court nonetheless granted summary judgment to the eye bank because “the Eye Bank removed the eyes of [the decedent] in justified reliance on the written permission form which was furnished by the Hospital.” *Id.* The good-faith defense under the Gift Act shielded the *Nicoletta* eye bank from liability.

A determination of good faith is measured against an objective standard. *See id.*; *see also Carey v. New England Organ Bank*, 446 Mass. 270, 282 (2006). As the court in *Nicoletta* noted:

[T]he legislature [in enacting the Gift Act] has created an objective standard by which the good faith of a donee could be measured. The Uniform Anatomical Gift Act establishes a statutory scheme which outlines the means of effecting an anatomical gift, the classes of individuals entitled to such gift, and the circumstances under which such a gift must be deemed null and void. None of the previous good-faith cases have involved such a definitive standard by which to judge a defendant’s conduct.

Nicoletta, 136 Misc. 2d at 1069. Thus, unlike other contexts of good faith involving a determination of an individual’s intent, the availability of the good-faith defense is an issue properly resolved by a Court on a motion for summary judgment. *See id.*; *see also Perry v. St. Francis Hosp. & Med. Ctr.*, 886 F. Supp. 1551, 1556-60 (D. Kan. 1995); *Lyon v. United States*, 843 F. Supp. 531, 533-34 (D. Minn. 1994).

In this case, the forms submitted by defendants LifeCell, RTI, Lost Mountain, and

Tutogen appear to be facially valid consent forms under New York law. (Vento Aff.; Wade Aff.; Hartill Aff.; Pering Aff.) The consent forms appear to be duplicates and are entitled “Biomedical Tissue Services Consent for Donation of Anatomical Gifts.” (*Id.*) In conformity with N.Y. Pub. Health Law § 4301(3), the forms state that “Helen Graves,” a “spouse” of Graves, “having no notice that this gift would have been opposed by the donor,” consents to the donation of specified tissues and/or bones.⁵ (*Id.*) In addition, the forms contain a mark indicating that BTS obtained “Telephone Consent” to the anatomical gift from Graves’s spouse. (*Id.*) Such telephonic consent was in accordance with N.Y. Pub. Health Law § 4303(5), which allows an anatomical gift to be “made by his telegraphic, recorded telephonic, or other recorded message.” Although no telephonic audio recording was made for these consents, the forms were signed and dated by two witnesses in conformity with 10 N.Y. Comp. Codes R. & Regs. § 52-3.3(b) (allowing telephonic consent to an anatomical gift if it is “recorded or documented in writing by the tissue procurement service requesting the donation”).⁶ Therefore, the consent forms facially complied with the regulations implementing the Gift Act.

The plaintiffs additionally argue that good-faith immunity is inapplicable in this

⁵ It is undisputed that “Helen Graves” was not, in fact, the spouse of Graves.

⁶ The plaintiffs’ reliance on *Carey* is misplaced. 446 Mass. at 281-82. In *Carey*, the Massachusetts Supreme Court looked at the statutory provisions of a similar provision allowing anatomical gifts to be made by recorded telephonic consent. *Id.* The court in *Carey* decided, as a matter of first impression, that the statutory language indicated that an audio recording was required for telephonic consent. *Id.* A mere transcription of the response was deemed not to comply with the statute. *Id.* In this case, New York’s administrative regulations specifically allow for either the audio recording or documentation in writing of a telephonic consent. 10 N.Y. Comp. Codes R. & Regs. § 52-3.3(b).

case, because the Tissue Bank Defendants knew or, at least, had constructive knowledge that the donor had not consented to the harvesting of tissue. (Pls.’ Br. 9-10; Jakab Aff. ¶¶ 7-9.) Evidence of such notice would negate the good-faith defense asserted by the Tissue Bank Defendants. *See Nicoletta*, 136 Misc. 2d at 1069 (granting summary judgment in favor of hospital because, *inter alia*, “[n]owhere in the pleadings or the transcripts of examinations before trial does it appear that the Eye Bank had actual notice that the gift was opposed by a member of any of the classes of individuals set forth in section 4301”); *see also Perry v. St. Francis Hosp. & Med. Ctr.*, 886 F. Supp. 1551, 1559 (D. Kan. 1995) (finding a material issue of fact regarding “actual notice of contrary indication” where plaintiffs submitted evidence that they “repeatedly expressed [to a hospital official] their opposition to removing [the decedent’s] eyes and bones”).

In support of their opposition to the defendants’ motions, the plaintiffs seek refuge in Fed. R. Civ. P. 56(f). Although the plaintiffs do not submit any affirmative evidence that the Tissue Bank Defendants knew of the relatives’ lack of consent, they have set forth in an affidavit that: (1) the Tissue Bank Defendants had actual or constructive knowledge of the lack of consent based upon “the patterns and similarities of the documentation” and their prior relationships with the other defendants; and (2) due to the stay of discovery in this case, information as to the knowledge of the Tissue Bank Defendants could not yet be provided. (Jakab Aff. ¶¶ 6-9.) The Tissue Bank Defendants deny this allegation both by way of legal memoranda and affidavits. They argue that they

were not aware that consent, in fact, had not been obtained from Graves's next of kin or that either Graves or his next of kin were in any way opposed to the donation.

Discovery has not commenced in this case on the issue of whether the Tissue Bank Defendants were aware that the consent forms were fabricated or that there was contrary indication by Graves or his next of kin. As these facts are essential in determining whether the Tissue Bank Defendants accepted an anatomical gift in violation of N.Y. Pub. Health Law § 4301(3) (prohibiting acceptance if the donee had notice that the decedent or his (or her) next of kin opposed such a gift), and whether the Tissue Bank Defendants are precluded from asserting good-faith immunity, the Court finds that a determination on the issue of good faith would be premature at this time. To accept the Tissue Bank Defendants' argument, that summary judgment could be granted based solely on the consent forms without examining whether the Tissue Bank Defendants knew that the consent forms were invalid, is to suggest that the Gift Act insulates potentially complicit tissue banks as long as they have received a completed consent form, even if there is evidence that the tissue banks knew, or had constructive knowledge, that the forms had been falsified. Such an interpretation would contravene the clear language of the Gift Act. Thus, the Court denies the motions for summary judgment brought by defendants LifeCell, RTI, Lost Mountain, and Tutogen.

CONCLUSION

For the reasons stated above, RTI, LifeCell, Lost Mountain, and Tutogen's

motions for summary judgment are **DENIED** at this time. An appropriate Order accompanies this Opinion.

s/William J. Martini

William J. Martini, U.S.D.J.

Dated: November 13, 2007